

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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GALDERMA LABORATORIES, L.P. and
TCD ROYALTY SUB LP, : CIVIL ACTION
:
Plaintiffs, :
v :
:
LUPIN INC. and LUPIN LIMITED, : 21-1710-SB
:
Defendants. :
- - -

Telephone Conference

Thursday, March 30, 2023 at 11:00 a.m.

- - -

BEFORE: HON. STEPHANOS BIBAS, U.S. CIRCUIT COURT JUDGE

- - -

APPEARANCES:

MORRIS NICHOLS ARSHT & TAYLOR, LLP
BY: JEREMY A. TIGAN, ESQ.

and

CAHILL GORDON & REINDEL LLP
BY: GERALD J. FLATTMANN, JR., ESQ.
And, ANDREW J. COCHRAN, ESQ.
(New York, New York)

Counsel for Plaintiffs Galderma
Laboratories, L.P. and
TCD Royalty Sub LP

REPORTED BY:

Brian P. Gaffigan, RMR, FCRR

1 **APPEARANCES: (Continued)**

2
3 **PHILLIPS, MCLAUGHLIN & HALL, P.A.**
4 **BY: JOHN C. PHILLIPS, JR., ESQ.**

5 **and**

6 **RAKOCZY MOLINO MAZZOCHI SIWIK LLP**
7 **BY: JOSEPH T. JAROS, ESQ.**
8 **And, ADRIANNE C. ROSE, Esq.**
9 **(Chicago, Illinois)**

10 **Counsel for Defendants Lupin Inc.**
11 **and Lupin Limited**

12 **Also present:**

13 **David Banchik**
14 **Chief Counsel**
15 **Galderma, S.A.**
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2 P R O C E E D I N G S

3 (REPORTER'S NOTE: The following Zoom
4 conference was held remotely, beginning at 11:00 a.m.)

5 THE COURT: Good morning.

6 MR. FLATTMANN: Good morning, Your Honor.

7 THE COURT: Are we waiting for anyone else
8 before we get going?

9 MR. TIGAN: Not for plaintiffs, Your Honor.

10 A VOICE: You are on mute.

11 MR. PHILLIPS: Your Honor, not for
12 defendants. We're all here.

13 THE COURT: Okay. Very good.

14 This is Judge Stephanos Bibas sitting by
15 designation in the District of Delaware in Case
16 Number 21-cv-1710, Galderma Laboratories versus
17 Lupin.

18 This meeting is being recorded to the
19 cloud. I'm joined off camera by my law clerk Henry
20 Walter. Why don't we get plaintiffs' counsel to
21 enter appearances and tell me who will be taking the
22 lead for plaintiffs in this case.

23 MR. TIGAN: Yes, Your Honor. This is
24 Jeremy Tigan with Morris Nichols in Wilmington for
25 Galderma. I'm joined by my co-counsel, Gerald

1 Flattmann and Andrew Cochran today, and Mr. Flattmann
2 plans to present our arguments.

3 THE COURT: Mr. Flattmann. I see
4 Mr. Cochran. I see -- so is it, did you say, Gerald
5 Flattmann?

6 MR. TIGAN: Yes, Your Honor.

7 MR. FLATTMANN: Yes, Your Honor.

8 THE COURT: Let's get your name up there.

9 And Mr. Cochran. What is your first name?
10 What's his?

11 MR. TIGAN: Andrew.

12 THE COURT: All right. We've got that.

13 And so Mr. Flattmann is taking the lead for
14 plaintiffs.

15 And who is here for defendants?

16 MR. PHILLIPS: Your Honor, it's Jack
17 Phillips from Phillips, McLaughlin & Hall in
18 Wilmington, and with me on the call are Joe Jaros and
19 Adrienne Rose from Rakoczy Molino. Mr. Jaros will
20 address the Court.

21 THE COURT: Okay. Joe Jaros, and you said?

22 MR. PHILLIPS: Adrienne Rose from Rakoczy
23 Molino.

24 THE COURT: Okay. So --

25 MR. TIGAN: Your Honor, I was remiss. I

1 should have noted, too, our client representative
2 David Banchik is on the call. He is Chief IP Counsel
3 at Galderma. I apologize for that.

4 THE COURT: Banchik. What is the ending of
5 your name, sir? C-K?

6 MR. BANCHIK: B-a-n-c-h-i-k.

7 THE COURT: Banchik. Okay. Sorry. There
8 is a D. Oh, I see, Chuck Banchik'd, that's what it
9 is.

10 MR. BANCHIK: No, this is a goofy IT
11 acronym.

12 THE COURT: Look, people who have, you
13 know, strange Greek names don't throw stones about
14 spellings.

15 All right. Very good.

16 So you said it's Mr. Flattmann for
17 plaintiffs and Mr. Jaros for defendants.

18 MR. PHILLIPS: Correct, Your Honor.

19 THE COURT: Very good. We are here on
20 defendants' motion for leave to amend, answer and
21 counterclaims, and the number of the dispute here is
22 how the extent to which plaintiffs have gone and
23 changed their theories such that defendants ought to
24 be able to argue indefiniteness.

25 So let me raise a few questions.

1 Let me ask, I'll just call them Galderma
2 and Lupin. I think it's a little clearer.

3 So Mr. Jaros is here for Lupin. What is
4 it that you think is really new about Galderma's
5 supplemental infringement contentions? I'll ask you
6 that, and then I will turn to Mr. Flattmann to
7 respond.

8 MR. JAROS: Thank you, Your Honor.

9 As we laid out in our reply on March 3rd,
10 what is really new is the test method that they
11 disclosed that were relied upon. And that test
12 method is the 4.5 pH in 40 minutes --

13 THE COURT: Right.

14 MR. JAROS: -- to determine immediate
15 release.

16 THE COURT: Okay. But it was clear from
17 the beginning that this was all about how much in
18 vitro and in vivo are synced up or different, and
19 there is reference in the patents to having changing
20 pHs in the GI tract and the acidic environments in
21 the stomach being different from intestinal fluids,
22 and, you know, so there, there are some references
23 to pH 4.5, pH sensitive layers, and greater pHs in
24 the small intestine.

25 So it's been clear from the beginning that,

1 you know, when you are dealing with enterics in
2 dissolution, you've got to deal with different
3 environments in different parts of the GI tract.

4 Mr. Jaros, do you dispute that?

5 MR. JAROS: We do, Your Honor.

6 THE COURT: Okay.

7 MR. JAROS: What Lupin's position is, is
8 with respect to their contentions.

9 THE COURT: Okay.

10 MR. JAROS: So the July 2022 contentions
11 did not even include the words "in vitro," would
12 not identify dissolution test method, and did not
13 expressly state that they were contending Lupin's
14 product contains a ratio of 30/10. Those words just
15 didn't appear.

16 On February 3rd of this year, for the first
17 time, Galderma disclosed its intention to rely on
18 what it calls biorelevant dissolution testing, but
19 there were no specifics, a series of references.

20 THE COURT: Right.

21 MR. JAROS: There was no test method
22 identified, and still there was no express
23 allegation --

24 THE COURT: Right.

25 MR. JAROS: -- that the Lupin products

1 contained 30/10.

2 THE COURT: But the nub here is, is this a
3 substantive change or is it a clarification? Because
4 if it's a clarification, I don't see the need to
5 allow the amendment. What makes this a substantive
6 change?

7 MR. JAROS: I would call it a substantive
8 disclosure. So this started in January when we
9 issued discovery saying if you contend Lupin
10 literally infringes, tell us what method. Tell us
11 how you would conduct the test to show that Lupin's
12 product contains 30/10.

13 And in response to that, in response to our
14 pressing them on what their actual contentions were,
15 on February 3rd, they had the broad disclosure of the
16 concept of biorelevant testing.

17 And then we pressed further. Days later,
18 we pressed further and said, what do you mean by
19 biorelevant testing?

20 And in response to those discovery
21 requests, on March 3rd they revealed their actual
22 theory that we literally infringed based on a method
23 that is nowhere disclosed in the patent. There is no
24 such method using 4.5 pH in the patent or in the
25 references they --

1 THE COURT: Let's talk about the '532
2 patent at column 6. The bottom of 6 to the top of 7,
3 there is a reference to delayed release profiles and
4 the changing pH of the GI tract.

5 Column 7, a little further down, there is a
6 reference to enteric materials, and, you know, the
7 environment of the stomach and what soluble at the
8 intestinal pH is.

9 A little further down on column 7, there
10 is references to the pH of below 4.5 and the pH
11 sensitive layer.

12 So it's clear from the patents on that,
13 we're going to be talking about how to measure and
14 track those pHs.

15 MR. JAROS: Lupin disagrees, Your Honor.
16 That's simply description of how the compositions are
17 intended to function throughout the body and the
18 purpose of an enteric coating.

19 THE COURT: Right.

20 MR. JAROS: It's not a test methodology.
21 It's not a literal infringement theory.

22 THE COURT: Okay.

23 MR. JAROS: Right? So under the original
24 contentions, it was an and/or. Maybe they'll assert
25 literal, maybe they will assert Doctrine of

1 Equivalents, maybe they will assert both.

2 On February 13th, for the first time, they
3 made it express we contend Lupin's composition
4 contains 30/10.

5 We immediately followed up and said under
6 what test? Identify a test anywhere where Lupin's
7 composition contains 30/10.

8 And that's how we ended up with the
9 March 3rd contention saying, oh, we can go into your
10 ANDA, a document we had since May of 2022, your ANDA
11 and your testing under a different method under
12 what is called a multimedia comparative dissolution
13 report. We will point you back to your ANDA and
14 we're going to interpret certain data in that ANDA
15 as proving you literally infringed with a ratio of
16 30/10.

17 That was new on March 3rd, never before
18 disclosed.

19 THE COURT: All right. Let me hear what
20 Mr. Flattmann wants to say about that.

21 MR. FLATTMANN: Thank you, Your Honor.

22 We have expressed the fact that we were
23 going to assert literal infringement from the very,
24 very beginning in our complaint, in vitro dissolution
25 testing, including the testing that was found out

1 of Lupin's own ANDA, it's Lupin's own data was a
2 giant part of the proofs and evidence in all the
3 preceding cases that defendants are aware of.

4 Our infringement theories were in our
5 original docketed 2022 infringement contentions. We
6 expressly stated in all of our claim construction
7 briefing that we were going to rely and intended to
8 rely on in vitro/in vivo correlations and a variety
9 of pH in vitro dissolution testing.

10 And that actually provoked Lupin in its
11 claim construction briefing to raise the specter of
12 indefiniteness for the very first time, and that was
13 before the deadline for amending the pleadings.

14 They subsequently requested an additional
15 week to decide whether or not to amend the pleadings,
16 and they decided not to even after noting our
17 theories in our claim construction briefing and in
18 our constant requests for discovery, which we have
19 attached as an exhibit to our opposition letter,
20 the in vivo/in vitro correlation data in testing
21 throughout discovery in this case ever since July of
22 2022.

23 So they have been consistently on notice
24 that in vivo -- in vitro/in vivo dissolution testing
25 over a variety of pHs was going to be a big part of

1 the evidence in this case, and this attempted hook
2 to excuse their belated motion to amend four months
3 after the fact and after they decided not to pull
4 the trigger even after raising the specter of
5 indefiniteness in their claim construction briefs
6 would result in an incredible prejudice to us.

7 They have been on notice, the additional
8 information that was included in the supplemental
9 infringement contentions, which, by the way, we haven't
10 even reached the deadline for those contentions yet.
11 It's some time next month for supplementation, Your
12 Honor. That was simply additional evidence that we
13 found through discovery in the ANDA materials that
14 Lupin produced. So they were also aware of that
15 evidence.

16 THE COURT: Okay. Where -- show me where
17 you think the patents disclose a single testing
18 method that requires a specific pH and a specific
19 timeframe. What are you relying on for that?

20 MR. FLATTMANN: Well, we're not, Your
21 Honor. We believe that the patents don't require one
22 specific testing method. And that is borne out in
23 Judge Stark's decision in the *Sun* case where he
24 expressly stated that, at pages 281 and 289 that it
25 doesn't matter whether the dissolution profile is the

1 same as a ratio, et cetera. What matters is whether
2 or not functionally you can use test and evidence to
3 show that these functional portion terms are met.

4 THE COURT: Well, let me get Mr. Jaros's
5 response on that.

6 How do you think that the patents are
7 limited to a single testing method and a specific pH
8 such that, you know, that connects up with your
9 argument that you don't infringe?

10 MR. JAROS: Yes, Your Honor. So Figure 3
11 is the dissolution profile --

12 THE COURT: Right.

13 MR. JAROS: -- which I believe Mr.
14 Flattmann stated at the *Markman* hearing. Figure 3 is
15 a dissolution profile of a ratio, and it provides two
16 parameters: 1.1 and a time point of two hours.

17 THE COURT: Okay. So it's labeled 1.1, but
18 also two of the figures have a label of pH 7 also.

19 MR. JAROS: They do, Your Honor. So that's
20 the second stage of the test. And I want to be very
21 careful to distinguish a test methodology that can be
22 very broad. We can talk about conceptionally in
23 vitro dissolution, but then I'm going to talk about
24 what the patent tells you to do to determine the ratio.

25 The patent says to determine the ratio, use

1 in vitro dissolution.

2 THE COURT: Right.

3 MR. JAROS: Figure 3 gives you the pH. And
4 the reason I focused on pH 1.1 is because that tells
5 you what your IR component is.

6 THE COURT: Okay.

7 MR. JAROS: And whatever is left over and
8 what doesn't dissolve by pH 1.1 at two hours is by
9 definition the DR portion, the remainder.

10 THE COURT: All right. What, what term or
11 terms? You don't identify what particular terms you
12 think are indefinite that you want to argue.

13 MR. JAROS: So, Your Honor, in our reply
14 brief, I believe we attempted to identify with
15 clarity the two terms. So it's 30 milligrams
16 immediate release -- this is on page 2 -- or
17 10 milligrams delayed release.

18 THE COURT: Okay. Is it the word release?

19 MR. JAROS: No.

20 THE COURT: Which part of that?

21 MR. JAROS: It's the entire phrase, Your
22 Honor. If you have the '532 handy, I can direct you
23 to an example there.

24 THE COURT: Okay.

25 MR. JAROS: So '532, claim 1, column 12.

1 THE COURT: Um-hmm.

2 MR. JAROS: "Consisting of (i) an immediate
3 release portion comprising a drug wherein the drug
4 consists of about 30 milligrams of doxycycline."

5 So the "about 30 milligrams doxycycline,"
6 the context of that entire phrase would be indefinite
7 if different tests give you different numbers.

8 THE COURT: Why isn't that, the pH or
9 the testing method a matter for fact-finding? Why
10 is it we just throw our hands up and treat it as
11 indefinite?

12 MR. JAROS: We definitely won't throw our
13 hands up, Your Honor.

14 So the way the record stands right now, I
15 believe Galderma has essentially conceded under the
16 pH 1.1 test, and this date is in the ANDA and in our
17 reports, that Lupin' product releases 22/18. It's
18 about 55 percent/45 percent. So under that test
19 described in the patents of pH 1.1, the number would
20 be 22.

21 Under their new theory at 4.5, depending
22 on how you interpret the data -- we don't agree with
23 it, but under their theory you can get an IR value
24 for Lupin's product of 30 if you wait four hours
25 (240 minutes) at a pH of 4.5.

1 Now, that is obviously the matter of
2 expert testimony. If they present that theory at
3 trial and the Court accepts it as evidence of what
4 the IR portion or the DR portion is, that would have
5 a noninfringing result, 22, and an infringing result,
6 30, a literally infringing result.

7 That is the basis of indefiniteness. Your
8 Honor is absolutely right, we'll need to hear expert
9 testimony on that. We'll need to see what their
10 theories are on June 2nd.

11 As Mr. Flattmann acknowledged, they can
12 still supplement, they can still throw in new
13 theories, new pHs, new methods, and all of that
14 will become part of the indefiniteness case and the
15 subject of expert testimony.

16 THE COURT: If we extend, if we allow this
17 amendment that you seek, would we need to extend fact
18 discovery?

19 MR. JAROS: We would not, Your Honor.

20 THE COURT: Okay.

21 Mr. Flattmann, do you beg to differ?

22 MR. FLATTMANN: I certainly do, Your Honor.
23 We haven't even received validity contentions from
24 defendant. And even now, I don't know what term
25 they're saying is indefinite. It's certainly not a

1 term that has anything to do with in vitro
2 dissolution because that term does not appear in
3 the patent claims. We're talking about evidence,
4 not about indefiniteness, and we added additional
5 evidence to our infringement contentions, as was our
6 right to supplement during discovery.

7 We, we certainly believe that if you were
8 to grant the motion, we, we believe that at this late
9 stage that would not be the correct ruling, that we
10 would need to extend the entire schedule.

11 We haven't received any fact discovery
12 relating to indefiniteness. We framed our entire
13 case based on the representation of defendants at the
14 very first scheduling conference that this is not a
15 case about invalidity, we will not raise invalidity
16 defenses. And as Mr. Jaros said, this was just an
17 infringement case.

18 And they argued that to get an expedited
19 schedule. They did get a somewhat expedited schedule
20 based on that representation. We would have needed
21 more time for discovery to begin with, and we
22 certainly do now with only seven days left on the
23 clock to take discovery and no invalidity contentions
24 in hand.

25 We also, Your Honor, have served no

1 interrogatories on this point, no requests for
2 production on this point, no RFPs on this point. It
3 even potentially, depending on what term they're
4 actually saying is indefinite, could implicate claim
5 construction issues, Your Honor.

6 So this, this is a giant can of worms
7 way too late in the game which is being attempted
8 based on a very flimsy, flimsy strand that the one
9 additional piece of evidence -- not a theory,
10 additional piece of evidence was added to our
11 infringement contentions, Your Honor.

12 THE COURT: Let me give Mr. Jaros the last
13 word, if he wants to reply.

14 MR. JAROS: I do, Your Honor. I just
15 want to focus the Court's attention on Exhibit 10 to
16 our letter. And that's where the Court will see
17 highlighting in yellow which is what was added on
18 February 3rd. That's the first time that the word
19 "vitro dissolution" appears in their contentions.

20 And then in blue, the Court will see that
21 this new theory of literal infringement that the
22 Lupin composition literally contains 30/10 is in
23 blue. And it's not an easy read. You have to
24 attempt to follow the logic about the different pH
25 and what they're pointing to in Lupin's study.

1 We don't agree with the interpretation,
2 but that very substantive addition in blue reflects
3 proof, and it's the first time we've had proof of
4 what they meant by some in vitro/in vivo test method,
5 a more biorelevant test method. What they're
6 calling, on February 3rd, a more biorelevant test
7 method, and then disclosed on March 3rd as pH 4.5 at
8 240 minutes.

9 That is a substantive disclosure which put
10 us on notice for the first time they would contend
11 there is literal infringement. That literal
12 infringement gave rise to an indefiniteness defense
13 which we could not have raised.

14 THE COURT: All right. So this is the blue
15 highlighting at pages 17 to 18 of Exhibit 10.

16 MR. JAROS: The blue highlighting. Yes,
17 Your Honor.

18 THE COURT: Okay. Yes.

19 MR. JAROS: That is where pH 4.5 appeared
20 for the first time, and they said for the first time
21 literally Lupin's product contains a ratio of 30/10.

22 THE COURT: Okay.

23 MR. JAROS: And one final note, Your Honor.

24 THE COURT: Okay.

25 MR. JAROS: The deadline to serve written

1 discovery passed, but they were on notice that we
2 intended to seek leave to amend, and they could have
3 issued discovery, and they already served discovery.
4 They served interrogatories on March 3rd directed to
5 their new theory, directed to a pH of 4.5, and also a
6 broader request directed to a pH of 2.0.

7 And two days ago, they took the deposition
8 of our primary witness, our primary corporate
9 designee, and half of the deposition was about this
10 theory. And the report that they identified, they've
11 had it since May 2022, but the blue highlighting you
12 see was the subject of a deposition two days ago.

13 So I don't see what additional discovery
14 they would need to take because our indefiniteness
15 defense is contingent entirely on their literal
16 infringement theory.

17 THE COURT: Okay. Mr. Flattmann, do you
18 want to say anything limited to what Mr. Jaros just
19 said about discovery that has already been taken and
20 produced on the blue highlighting and the pH 4.5?

21 MR. FLATTMANN: I do, Your Honor.

22 The additional material that he is
23 referring to is no different from what was already
24 before defendants earlier in the case. We said that
25 the 30/10 ratio was met literally in our complaint,

1 and we said so multiple times during discovery and
2 in our claim construction papers, which is what led
3 them to raise that specter of indefiniteness way back
4 then.

5 This is simply additional evidence that
6 comes directly from materials that Lupin submitted to
7 the government in order to obtain approval for its
8 product.

9 THE COURT: Okay. Just a moment.

10 (Pause.)

11 THE COURT: All right. Thank you, all.

12 The Court is going to deny the motion.
13 It's not that I don't see a reason why people
14 couldn't argue about this, but fundamentally I don't
15 think Galderma has shifted its ground. It has
16 clarified, it's been clear that the fight all along
17 has been over in vitro, and we have some more
18 specificity here, but I don't think it's really a
19 different ground.

20 I agree that this is an infringement case,
21 not an invalidity case. I see from the face of the
22 patents and in the arguments that the pH levels of
23 the, you know, stomach versus intestine have been
24 here all along, even though there are some figures
25 labeled pH 1.1 and pH 7.

1 I find it telling that Lupin can't really
2 tell me what is indefinite about 30 milligrams
3 immediate release and 10 milligrams delayed release.
4 I mean I think there is an argument over the word
5 "release," and I think that is ultimately going to be
6 an argument for fact-finding that needs to be done at
7 trial.

8 I also do think we would need to reopen
9 discovery and delay this case, and this case is on a
10 tight timeline that Lupin itself has wanted to move
11 the case along.

12 So I'm denying it. I will do so with an
13 oral order today. And I'd like to know if there is
14 anything else the parties would like from me, any
15 assistance in moving this case along promptly.

16 MR. JAROS: Your Honor, on behalf of Lupin,
17 we do have a couple of potential discovery disputes.

18 THE COURT: Okay.

19 MR. JAROS: We're are awaiting depositions
20 about Galderma. Galderma has assured us just earlier
21 today that they are going to provide dates for those
22 depositions very soon. So we don't anticipate there
23 will be a dispute, but we just want to let the Court
24 that --

25 THE COURT: All right.

1 MR. JAROS: -- we're awaiting.

2 THE COURT: I think it's very fair to say
3 that, you know, if Galderma is getting the benefit of
4 its expedited scheduling in my keeping, you know, all
5 the invalidity claims out, you know, what is good for
6 the goose is good for the gander. I expect Lupin
7 likewise to live with the impending discovery
8 deadline and to make, you know, every effort to make
9 those witnesses available within the deadline.

10 Mr. Flattmann, are you going to be able to
11 do that?

12 MR. FLATTMANN: Yes, Your Honor. Not --
13 we've agreed that we would be able to do so very
14 shortly thereafter. That was the subject of the meet
15 and confer that my colleague had with Mr. Jaros
16 earlier today.

17 THE COURT: Very good. Very good. I will
18 hold you to that. I thank you all, and please be in
19 touch with my clerk Henry Walter at, you know, the
20 earliest sign that something requires the Court's
21 attention.

22 MR. FLATTMANN: Thank you, Your Honor.

23 THE COURT: You're welcome. All right.

24 MR. PHILLIPS: Thank you, Your Honor.

25 THE COURT: And you are all welcome. This

1 has been recorded to the cloud. If either side needs
2 a copy of it or have it transcribed or anything else,
3 just email Mr. Walter and he can make the link
4 available to both of you, both sides.

5 MR. FLATTMANN: Thank you, Your Honor.

6 THE COURT: All right. Good-bye.

7 MR. JAROS: Thank you.

8 (Telephone conference ends.)
9

10 I hereby certify the foregoing is a true and
11 accurate transcript from my stenographic notes in the
12 proceeding.

13 /s/ Brian P. Gaffigan
14 Registered Merit Reporter
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